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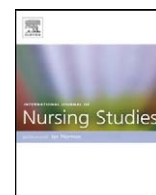
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Telemonitoring in patients with heart failure, the TEHAF study: Study protocol of an ongoing prospective randomised trial

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ABSTRACT

Background: As the prevalence of heart failure (HF) rises sharply, the costs related to the care of these patients increases in parallel. Considering the already limited resources and manpower, in the future the demand for care may exceed the supply. Therefore, health care systems are encouraged to develop innovative strategies to deal with the burden of HF to improve the quality of care in order to medical outcomes and patients' quality of life. For that reason new management systems – such as telemonitoring – have to be explored. **Objectives:** This paper outlines the study protocol of a tailor-made telemonitoring program in ambulant patients with HF.

Design and methods: A prospective randomised controlled trial is carried out at 3 hospitals in the South-Limburg area in the Netherlands. Primary outcome measures are hospital admissions and cost-effectiveness. Secondary outcomes are effects on therapy compliance, level of disease specific knowledge and quality of life. Also determinants are studied of most and less benefited patients in the intervention group.

Power calculation: It is estimated that 390 patients have to be included in the study, with 185 in each arm.

Results: Inclusion started in September 2007 with a follow-up time of 12 months. First results are expected at the end of 2010.

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What is already known about the topic?

- Non-adherence resulting in increased hospitalisations is common in patients with HF.
- Telemonitoring is one of the recently developed as part of chronic care management systems in patients with HF; however randomised controlled trials are lacking to proof its (cost-) effectiveness.

- The majority of the telemonitoring systems focuses on vital signs such as blood pressure, rate control and weight.

What this paper adds

- This paper presents a study of the value of a telemonitoring system, using a randomised controlled trial design.
- It focuses on education, adherence and self-management as a means to reduce symptoms or detect those at an early stage, rather than monitoring just vital signs using communication programs, tailored to the patients needs.
- To better meet with the specific patient needs, four telemonitoring programs were designed with different

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emphasis on the dialogues about knowledge, compliance and symptoms respectively.

1. Background

The most effective strategies to control chronic diseases contain multiple components as recommended by the European Society Guidelines (Dickstein et al., 2008; Coleman et al., 2009). Of these components, the most challenging is patient education (McAlister et al., 2004; Yu et al., 2006). Patient education is based on the assumption that giving information results in knowledge and skills gain. The majority of studies shows positive influences on the outcome of HF patients, although it is not clear which information is best for which patient (Yu et al., 2006). Although the body of educational programs for heart failure patients is extensive (Dickstein et al., 2008), knowledge is limited how these methods match with the patients needs. Moreover, the majority of patients with HF is 65 years of age or older, being a possible challenge for education programs to be effective (Yu et al., 2006). Comorbidities such as diabetes, chronic lung and renal failure, peripheral atherosclerosis, depression and/or personality disorders are additional hurdles for patients to deal with (new) information and about how to deal best with health issues (Sloan and Pressler, 2009; Braunstein et al., 2003).

Patient education is an important component in the management of HF and should be provided through effective and well-evaluated integrated care strategies. HF education can further be improved by combining oral or written communication with new technologies such as telemonitoring (TM) (Strömberg, 2005). Trying to make TM applications generalizable to the HF population at large, may often fail to meet particular patient needs. Therefore subpopulations have been suggested to be categorized based on variables such as age, gender, specific medical problems, chronic disease, or cultural aspects and accordingly education should be adjusted to these categories (Alverson et al., 2008).

This article describes the design of a randomized controlled trial aiming at evaluating a TM system the Health Buddy® in HF patients, using tailor-made TM programs for patients with HF as the intervention, the TEHAF study. The development of the tailor-made program is based on the experience with the Health Buddy® in a preceding pilot study in the participating centres of Heerlen (Atrium Medical Centre), Maastricht (University Medical Centre) and Sittard (Orbis Medical and Care Concern), situated in the South-Limburg, the Netherlands (Boyne et al., 2008).

2. Methods

2.1. Study population

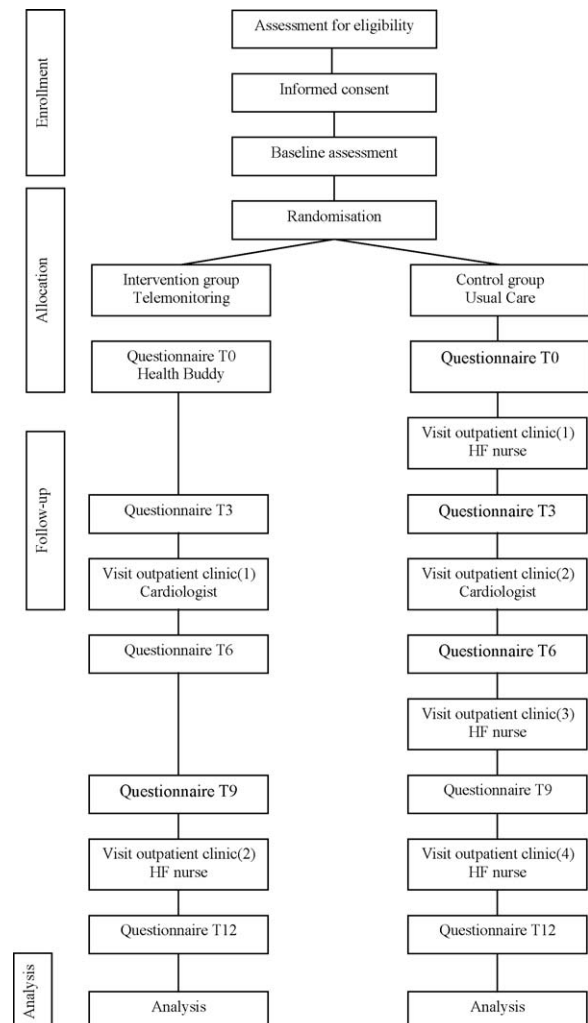
Eligible for inclusion are patients with chronic HF New York Heart Association (NYHA) classes II–IV treated by a cardiologist and in care of a HF nurse (HFN). Selection of patients occurs in the outpatient clinic from one of the participating centres and in the home situation when

patients are visited by a HFN. Patients are excluded if being unable to give informed consent, have visual limitations, hard of hearing in combination with living as a single person, did not have command of the Dutch language, were planned for a hospital admission within 3 months and/or suffer from chronically obstructive pulmonary disease, Parkinson's disease, extracorporeal dialysis, (pre)dementia or another disease with a expectedly shortened life span.

2.2. Study design

A prospective, randomised controlled trial is conducted with a follow-up period of 12 months. Cardiologists and HFN select patients with HF, whereas the research nurses contact the patient in case of eligibility. After given informed consent, patients are randomised by a dedicated software system (SPSS 15.0) either to the control group, receiving usual care according the European guidelines or

Table 1
Study design.



to the intervention group, receiving the Health Buddy[®]. Before start of the intervention (T_0) patients fill out a questionnaire. Patient's baseline characteristics are retrieved from the medical chart. Follow-up questionnaires are released after 3, 6, 9 and 12 months (Table 1).

2.3. Study hypotheses

The hypotheses are tested that the admission rate for HF is lower in the intervention group than in the control group and that TM is cost-effective compared with usual care.

2.4. Primary objective

The primary objectives are to study the effectiveness of the Health Buddy[®] in terms of hospital admissions for HF and cost-effectiveness, as expressed in costs per quality adjusted life years (QALY's). Also quality of care is studied, comprising mortality, planned and unplanned HF related contacts with caregivers.

2.5. Secondary objectives

Secondary objectives are:

- (1) to study outcomes in terms of therapy adherence, level of disease specific knowledge and quality of life;
- (2) to demonstrate patient determinants affecting the outcomes of the Health Buddy[®] in terms of care consumption, level of knowledge and adherence.

3. Intervention

3.1. The Health Buddy[®]

The Health Buddy[®] is an easy-to-use device with a liquid crystal display screen and four buttons to answer questions provided in daily dialogues. The responses to

the dialogues are sent to a protected server and successively to the caregivers' i-Care desktop (Table 2). Patients' responses to the dialogues are transferred into risk profiles (low, medium or high) and ordered according to risk level. Consequently, care providers are able to quickly select high-risk patients and anticipate to their problem. The involved care providers consist of specialized HFNs, a nurse assistant and a supervising cardiologist. The HFNs are highly educated in chronic heart failure at the level of an advanced medical student, and are very experienced regarding HF care. The nurse assistant is a caregiver at a lower educational nursing level being instructed before and coached by a HFN during the study.

The original English content of the Health Buddy[®] was translated into Dutch by the distributing company (Sananet) and adapted to the Dutch health care situation and European guidelines (Dickstein et al., 2008) by a cardiologist (AG) and a HF nurse practitioner (JB). Sananet was responsible for the final layout whereas the health care providers were finally responsible for the content.

3.2. Content of the program

The content of the Health Buddy[®] covers scheduled dialogues about three domains: symptoms, knowledge and behaviour respectively. The total amount of dialogues counts 145 different combinations, yet the combination of dialogues changes day by day. The questions are answered by selecting one of the four keys. If the answer is correct, this is confirmed by the system, whereas in case of an incorrect response, the right answer is provided. In this way knowledge increases both by correcting and by repetition of dialogues.

In case of repeated mistakes after 3 months, the nurse assistant will contact the patient and explain the misunderstood issues. Patients at high risk for symptoms will always be approached by a HFN since the start of the program.

Table 2
The Health Buddy[®] system.

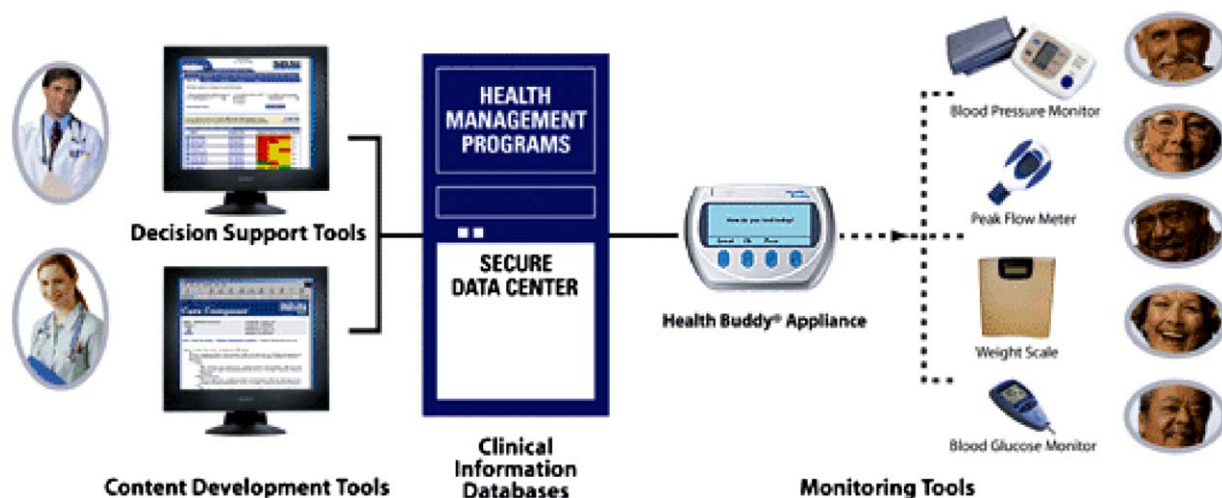


Table 3
Characteristics of the programs.

	Symptoms	Education/adherence	Days
Program 1	+	+	90
Program 2	+	+/-	30
Program 3	–	+	90
Program 4	–	–	180

+: Strongly focused on; +/-: moderate focused on; – less focused on. Program 1: contains a high level of monitoring symptoms and a high level of education: at the start all patients are allocated at this program. Program 2: contains a high level of monitoring symptoms and a lower level of education: patients allocated at this program are indicated for intensive monitoring because of severe heart failure or many complaints. Their disease specific education level allows a less intensive education program. Program 3: contains a low level of monitoring symptoms and a high level of education: patients with few complaints and a low disease specific education level are allocated to this program. Program 4: contains a low level of monitoring symptoms and a low level of education: patients with few complaints and a high level of disease specific education are allocated to this program.

3.3. The tailor-made aspects of the content

Primarily the goal of the foregoing feasibility study was to study whether patients were able to handle a TM system, and secondly that the provided information was sufficient for care providers to monitor patients at a distance. Focused interviews with patients and HFNs showed a high satisfaction with the system, but a need was felt for more flexibility of the content, regarding the emphasis of monitoring in relation to knowledge and behaviour or to symptoms (Boyne et al., 2008). Because no such differentiated TM contents were available, self-designed combinations of dialogues were used for that purpose. The first step to tailor the content was the assessment of distinguishing characteristics in HF patients, regarding symptoms, level of disease specific knowledge

and behaviour (Van der Wal et al., 2006; Miller-Davis et al., 2006). Out of a combination of these characteristics four programs are constructed. The main difference between the programs is more or less emphasis on symptoms or education. The duration of the programs differs from 30 to 180 days (Table 3). During the first 90 days all patients receive the same program. At the last day of each program a calculation is made about the number of high risk labels in the last 30 days. The result of this calculation indicates the allocation to the next program (Table 4).

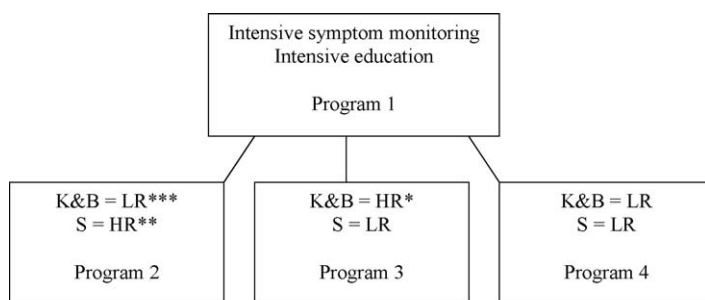
Always the decision is made about allocation to a next level program as described in Table 4, except for two situations. The first situation is after a HF admission: then always allocation to program 2 is done for the duration of 30 days, independent of the preceding program before admission. The second exception regards patients waiting for a heart transplantation; they are always allocated to program 2.

Another way to tailor the program, additional to the before mentioned programs, is the possibility to switch off parts of the content. This can be used in case specific information is not applicable for a certain patient, such as information about nitro-glycerine, beta-blocker, ACE-inhibitors, ARB antagonists, potassium saving diuretics and digitalis.

3.4. Procedure

Patients complete the daily dialogs on a self-selected moment. The pilot study showed that depending on the answers, the time to complete the dialogues varies between 3 and 10 min. The Health Buddy[®] gives an option to review the dialogues at the end of the session. The HFN and nurse assistant check the dialogues on a daily basis except for the weekends. The mean handling time per

Table 4
Program allocation criteria.



K&B = Knowledge & Behaviour, S = symptoms, HR = high risk, LR = low risk

* K&B = HR: an amount equal or more then 4 high risk alerts on knowledge or behaviour, or the sum of both during the last 30 days;

** S = HR: an amount of 4 high risk alerts on symptoms during the last 30 days, or 2 high risk alerts on symptoms during the last 15 days, or 1 high risk alert on symptoms during the last 7 days

*** K&B = LR (or) S = LR : none or less HR alerts as described in K&B = HR or S = HR.

patient was previously found to be 2 min and 20 s/day including both checking the dialogues and the related actions (Boyne et al., 2008).

Patients, spouse or family member in the intervention as well as in the control group receive verbal and written information according to the European Guidelines (Dickstein et al., 2008). Patients are instructed about signs and symptoms of HF, self-management as actively seeking help in case of progressive dyspnoea, weight gain and oedema, importance of medical and non-medical therapy compliance, salt and fluid restriction, importance of physical activity and other, more patient tailored information. Instructions were given for seeking help outside the office hours. The information supplied by the TM system is additional to the usual care information.

For the intervention group 2 face-to-face contacts per year were scheduled consisting of one to the cardiologist and another one to the HFN. Telephone contacts with the HFN or nurse assistant in response to a Health Buddy[®] alert, were considered as planned contacts. Patients assigned to the control group were planned to have 4 visits, including 1 to the cardiologist and 3 to the HFN (Table 1). Unscheduled contacts with a care provider were allowed at any time for both patient groups. In two of the participating centres, depending on patients' mobility, contacts with the HFN took place either in the outpatient clinic or by a home visit.

4. Study measures

4.1. Instrumentation

All patients are asked to fill out an extensive questionnaire at baseline (T_0), after 3, 6 and 9 months and after the follow-up period of 1 year (T_{12}). Information is gathered about prescription of medication, medical history and socio-demographics. Measurement of quality of life occurs by means of Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green et al., 2000) and the EQ 5D (Brooks et al., 2003), disease specific knowledge by the Dutch Heart Failure Knowledge Score (DHFkSc) (Van der Wal et al., 2005) and self-management by the European Self Care Behaviour Scale (ESCBSc) (Jaarsma et al., 2003). Adherence for pharmacological and non-pharmacological prescriptions and depression are measured by respectively the Heart Failure Compliance Questionnaire (HFCQ) (Evangelista et al., 2001) and the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983). Dyspnea and tiredness are assessed by the Borg scale (Borg, 1982), self-efficacy by the Barnason Efficacy Expectation Scale (Barnason et al., 2002) and personal individual characteristics by the DS-14 (Denollet, 2005). Care consumption and mortality are based on hospital registration, costs by hospital registration and a cost-diary filled out by the patients. Comorbidity is assessed by the Charlson index (D'Hoore et al., 1996) (Table 5).

4.2. Power

A sample size of 188 patients in both arms was calculated, based on a minimum reduction of 38% and a

Table 5

Methods and questionnaires.

	Assessment
Cardiovascular hospitalisation/death	12 months
Comorbidity	12 months
Self-care	Baseline, 3, 6, 9, 12 months
Compliance	Baseline, 3, 6, 9, 12 months
Dyspnea/tiredness	Baseline, 3, 6, 9, 12 months
Depression	Baseline, 3, 6, 12 months
Self-efficacy	Baseline, 3, 6, 12 months
Disease specific quality of life	Baseline, 3, 6, 12 months
Quality of live (costs)	Baseline, 3, 6, 12 months
Disease specific knowledge	Baseline, 3, 6, 9, 12 months
Personal individual characteristics	Baseline
Classification of heart failure	Baseline, 12 months
Costs	Baseline, 3, 6, 9, 12 months

maximum reduction of 48% for hospitalisation for heart failure (Boyne et al., 2008; Bondmass et al., 2001; Macropoulos and Knoop, 2003), using an alpha of 0.05 and a power of 0.80. To compensate for non-evaluable patients, we planned to enroll 10% more patients for both groups. Therefore, a total of 390 patients will enroll into the study.

4.3. Statistical analysis

Data will be analysed according to the intention-to-treat principle, using SPSS statistical software (SPSS 15.0). Stratified data analysis per centre will be performed. The primary objective, number of admissions for heart failure will be evaluated by the Kaplan Meier survival analysis. Categorical variables will be presented as the observed number and percentage, whereas the continuous variables will be reported as the mean standard deviation. Differences for continuous variables will be tested with the independent *t*-test. Further multivariate techniques will be used to adjust for possible differences in baseline characteristics and scores. Comparison of observations between the groups, considering the different locations will be analyzed by the MAN(C)OVA test for repeated measures. The *P*-value of <0.05 will be considered as statistically significant.

4.4. Clinical endpoint

An independent panel, consisting of an independent HF cardiologist (chairman), geriatrist and nephrologist, is compiled to adjudicate whether hospitalization and/or death is related to HF in terms of this protocol. The committee is blinded to study arm assignment, and members independently review each case in order to classify a HF related admission or death. The independent opinions are reconciled at a panel meeting. In case of lacking unanimity, the case is discussed during the meeting with the aim to develop consensus. By unremitting non-unanimity the endpoint will be established by the chairman.

Conflict of interest. None declared.

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Registration and Ethical approval. The study is registered as a clinical trial at Clinicaltrials.gov (identifier NCT00502255) and ethical approval was obtained from the Medical Ethical Committee of the 3 participating centres, according the declaration of Helsinki (Rickham, 1964).

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